REMARKS

Claims 13-16, 18, 19 and 27-29 presently appear in this case. Claims 18, 19, 27, 28 and 29 have been withdrawn from consideration. Claims 13, 15 and 16 have been rejected. Claim 14 has been objected to but has been indicated to be allowable if rewritten in independent form. The official action of February 26, 2003, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, the present invention relates to an isolated polypeptide which is capable of binding to RIP, which protein is a RIP-associated protein (RAP) encoded by a DNA sequence in a clone deposited in a depository, a fragment thereof which binds to RIP, an analog thereof having no more than 10 changes in the amino acid sequence of RAP, each said change being a substitution, deletion or insertion of an amino acid, which analog binds to RIP, or a derivative thereof by modification of a functional group which occurs as a side chain or a terminal group without changing one amino acid to another.

The interview between the undersigned attorney and examiners Huynh and Chan on July 1, 2003, is hereby gratefully acknowledged. In this interview, applicant proposed to delete "and modulating or mediating the intracellular activity of RIP" from the preamble of claim 13 so as to obviate the

enablement rejection. The appropriateness of the art rejection in view of the applicable case law was also discussed. The arguments presented at the interview will be stated in the present remarks. The examiners agreed to reconsider the rejections in light of this proposed amendment and the remarks made at the interview.

It is noted that the examiner has reconsidered and retained the restriction requirement. Applicant's grounds of traversal remain and Applicant retains the right to file a petition to the Commissioner under 37 CFR 1.144 at an appropriate time.

Claims 13 and 15-16 have been rejected under 35 USC 112, first paragraph, because the specification, while being enabling for an isolated polypeptide comprising SEQ ID NO:2, which is capable of binding to RIP, or a RAP protein encoded by the DNA sequence of the deposited clone, does not reasonably provide enablement for any fragment of RAP, any analog of RAP, any derivative thereof or any composition for treating any disease. The examiner states that the specification does not teach how to make or use such fragments, analogs or derivatives because binding or association does not equate to having a specific biological function, not to mention modulating any intracellular activity. This rejection is respectfully traversed.

Claim 13 has now been amended to delete reference to modulation or mediation of the intracellular activity of RIP. All that is required of the fragments, analogs and derivatives of RAP set forth in Claim 13 is that they bind to RIP. There is no necessity for any biological activity set forth in this polypeptide claim. It is irrelevant that biological activity is mentioned in the specification, insofar as the consideration of claims 13, 15 and 16 are concerned. The specification discloses, in paragraph 119 on page 58, that the RAP protein or its analogs, fragments or derivatives may be used in methods of affinity chromatography to isolate proteins which are capable of binding thereto. In order to satisfy the how to use requirement of 35 USC 112, first paragraph, one need enable only a single utility. Note the last sentence of MPEP 2164.01(c), which states:

> In other words, if any use is enabled when multiple uses are disclosed, the application is enabling for the claimed invention.

All of the examiner's arguments go to the unexpected nature of the biological activity. However, the non-biological affinity chromatography utility is enabled, and this all that is necessary to satisfy the enablement requirement of the first paragraph of 35 USC 112. The examiner has not explained why it would take undue experimentation to determine whether any given analog or

fragment or derivative binds to RIP. A binding assay is a simple and quick assay which can be done with high throughput. The analog claims are not broad as they require 98% identity. It would not take undue experimentation to make random mutations as disclosed in the specification and determine whether or not they bind to RIP by means of the assays disclosed in the specification. The same is true for fragments. Modification of functional groups that occur as side chains without changing one amino acid to another would not be expected to change the binding properties. In any event, any such derivative could be readily tested for binding without engaging in undue experimentation. As the rejection is based on biological utility and as claim 13 requires no biological activity, reconsideration and withdrawal of this rejection is respectfully urged.

With respect to claim 16, this claim is not directed to a pharmaceutical composition, but only a composition. RAP in water for any purpose is such a composition. It is not intended that any of the present claims be directed to the treatment of a disease or that they require any pharmaceutical purpose. The composition of claim 16 can be used to make an affinity column. The polypeptide must be in a pharmaceutically acceptable carrier in order to cause it to bind to an affinity chromatography column. Thus, claim 16

does not require a biological activity. If any utility is enabled, then the claim is enabled. Accordingly, claim 16 is enabled for the same reasons as discussed above with respect to claim 13 from which it depends. Reconsideration and withdrawal of this part of the rejection is also respectfully urged.

Claims 13, 15 and 16 have been rejected under 35 USC 102(e) as being anticipated by Harper. The examiner states that SEQ ID NO:47 of Harper is a fragment of the claimed polypeptide of SEQ ID NO:2 and therefore anticipates the claims. The examiner states that the present application has an effective filing date of March 19, 1998, while the Harper patent has an effective date of October 16, 1997. The examiner states that the polypeptide of SEQ ID NO:47 of Harper has support in the parent application and therefore has an effective filing date of 1997. This rejection is respectfully traversed.

As explained at the interview, the examiner is incorrect as a matter of law that the effective filing date for the Harper patent can be the same as that of its parent merely because SEQ ID NO:47 appears in the parent. A patent is only available as of its effective filing date in view of 35 USC 102(e). A patent may only have the effective filing date of its parent for the purpose of 35 USC 102(e) if the

patent is entitled to a right of priority to the earlier date under 35 USC 120. MPEP 2136.03 IV is entitled:

> PARENT'S FILING DATE WHEN REFERENCED AS A CONTINUATION IN PART OF THE PARENT

The first sub-heading is:

> Filing Date of U.S. Parent Application Can Only Be Used as the 35 USC 102(e) Date If It Supports the Claims of the Issued Child

As stated in MPEP 2136.03 IV:

> In order to carry back the 35 USC 102(e) critical date of the U.S. patent reference to the filing date of a parent application, the parent application must (A) have a right of priority to the earlier date under 35 USC 120 ... and (B) support the invention claimed as required by 35 USC 112, first paragraph.

This is supported by *In re Wertheim*, 646 F.2d 527, 537, 209 USPQ 554, 564 (CCPA 1981).

The parent application of Harper does not support the invention claimed as required by 35 USC 112, first paragraph. Thus, it is irrelevant that it contains a disclosure of SEQ ID NO:47, as the disclosure of a protein in an abandoned application to which an issued patent is not entitled to priority under 35 USC 120 is not available as a reference under any section of 35 USC 102.

In the interview, the examiners indicated that they would review the law on this matter. It is urged that a review of MPEP 2136.03 IV will establish that the Harper

patent is not entitled to the effective filing date of its parent application. None of the claims of Harper are supported by the disclosure in the parent application. All of the claims of Harper are supported only by the new matter added to the 1998 application. Accordingly, the 35 USC 102(e) date for Harper is October 15, 1998. The effective filing date of the present application is March 19, 1998. Accordingly, Harper is not available as a reference.

The examiner states that the effective filing date of the present application is September 20, 1999, because it is a CIP of 09/381,358. However, in contrast to the situation for Harper, the present claims are supported by application 09/381,358, and therefore the present claims are entitled to the effective filing date of March 19, 1998. See MPEP 706.02, paragraph (B) under the heading, "DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION," where it states:

> (B) If the application is a continuation-in-part of an earlier U.S. application ... [a]ny claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of the parent application.

If the examiner does not believe that the present claims are supported by the parent, then it is requested that the examiner point out exactly why she takes this position. As long as the claims are supported in the manner required by 35 USC 112, first paragraph, by the disclosure of the parent

case, it does not matter if the parent case is a continuation-in-part or a continuation of a divisional.

For all of these reasons, reconsideration and withdrawal of this rejection are respectfully urged.

The examiner's indication that claim 14 would be allowable if rewritten in independent form is noted. However, as it is believed that claim 13 from which it depends is now in condition for allowance, claim 14 will not be rewritten into independent form at this time.

It is submitted that all the claims now present in the case clearly define over the references of record. Reconsideration and allowance are therefore earnestly solicited.

Respectfully submitted,

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